UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

Civil Action No.: 08 CV 2060 (JAP)

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

DOCUMENT ELECTRONICALLY FILED

Motion Date: May 3, 2010

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BRIEF IN SUPPORT OF DEFENDANTS SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC'S MOTION FOR SUMMARY JUDGMENT AND TO PRECLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WARREN LIEBERMAN

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PRELIMINARY STATEMENT

This is a product liability action filed by plaintiff, Robert Jones, against defendants, Synthes USA Sales, LLC and Synthes USA Products, LLC ("Synthes), relating to the Synthes Anterior Tension Band System ("ATB"). (See First Amended Summons and Complaint at Ex. C) Plaintiff claims that an ATB implanted by his physician, Dr. Marc Levine, during July 2005 spinal fusion surgery was defective because two of the four ATB screws broke ten months after the surgery.

Plaintiff's surgeon, Dr. Levine, Dr. Joel Spielman, a spine surgeon retained by Synthes, and Dr. Lyle Zardiackas, a metallurgist and biomechanical expert retained by Synthes, agree that breakage of the screws resulted from plaintiff's failure to achieve bony fusion across the L5-S1 vertebral space in the ten month period following surgery. The failure to fuse caused micro-motion of the fusion construct and metal fatigue to the ATB. (Levine Dep., p. 89-90 at Ex. R; Spielman Aff., ¶ 4 at Ex. H; Zardiackas Aff., ¶ 20-21 at Ex. I) The risk of device breakage from a lack of bony fusion is well known in the field of internal fixation devices, orthopedics and fusion surgery.

Plaintiff's claims of product defect are based solely on the opinions of his expert, Warren Lieberman, a former airplane engineer with no education, experience or training in internal fixation devices, biomechanics, orthopedics or spinal fusion surgery. (See Lieberman CV at Ex. E) As set forth in the Daubert section of this motion, Mr. Lieberman is a metallurgical engineer who spent thirty-four years of his

career at the Boeing Company responsible for airplane design. (See Lieberman CV at Ex. E) While Mr. Lieberman seeks to offer opinions on fusion surgery, biomaterials, and internal fixation devices, he has no discernable education, training or experience in these areas. His testimony revealed that he is neither a physician nor a spine surgeon; he has never consulted or testified before on any implantable surgical device case; he does not have any education training or experience in the field of medical devices; he has never been employed by or consulted for a company that designs, manufactures or tests medical devices; he has never designed a medical device; he has never conducted a clinical trial of a medical device; he is not a member of any professional organizations that deal with medical devices; he has never published any scientific papers with respect to medical devices; he has never studied, and has no formal training in, the field of biomechanics; he has never studied the application of metal in an implantable surgical device; he has no formal training in orthopedics and has never observed a surgical procedure; he has never taught or given any lectures on spinal surgery, orthopedic surgery, medical devices, biomechanics or the effect of blood, body tissue and bone on implantable surgical devices; he has never written any peer reviewed articles on medical devices; and he has no expertise in testing implantable medical devices or analyzing the cause of the breakage of a surgical screw.

Mr. Lieberman intends to offer speculative testimony that had Synthes used certain manufacturing methods (shot peening and gray anodization), which have not

been validated or tested, the screws would have lasted longer. Whether the screws would have lasted a day, a week, a month or a year longer, Mr. Lieberman has no idea because he never tested his alternative design theories on an exemplar ATB or on any cancellous bone screw similar to the type used in the ATB. He also opines that had Synthes used a testing method called dye penetrant testing, it *may* have discovered a surface flaw in the screw which he suggests *may* have been present. Mr. Lieberman cannot opine whether a flaw was present because the broken screws were never removed from plaintiff because, according to Dr. Levine, they were well embedded in bone, were not impinging on the nerve canal and thus were doing no harm. (Levine Dep., p. 123-124 at Ex. R)

Synthes moves for summary judgment on the grounds that plaintiff has no reliable evidence that the ATB was defective in manufacture or design, or that Synthes did not adequately warn about the risks of the device. In addition, based on plaintiff's failure to retain a medical expert, he cannot establish causation i.e. that his present complaints were caused by the breakage of the ATB's screws rather than from disc disease at other levels of his spine that pre-existed his surgery; that the limited goals of his surgery, a reduction rather than elimination of pain, were not achieved; or that his second surgery was needed because of the broken screws rather than his failure to fuse. Without these elements, plaintiff cannot make out a *prima facie* case of product liability under New Jersey's Product Liability Act, N.J.S. 2A:58C-1 through C-7 ("NJPLA").

Synthes also moves to preclude plaintiff's expert, Warren Lieberman, from testifying. It is respectfully submitted that Mr. Lieberman's opinions must be excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) because he lacks sufficient education, experience and training in the field of internal fixation devices, biomaterials, orthopedics or, spinal fusion surgery to offer reliable testimony on these topics. As to methodology, his alternative design/manufacturing/inspection methods, i.e. shot peening, gray anodization and dye penetrant inspection, which he claims would have improved the fatigue life of the ATB and/or revealed a flaw in the ATB, are not supported by reliable methodology. Mr. Lieberman has neither tested nor validated these methods to determine whether they would improve fatigue life or for safety, feasibility or efficacy. He has not submitted the application of these methods to cancellous bone screws of the type used in the ATB for peer review. He cannot cite any scientific studies supporting the use of these methods for cancellous bone screws. He has not performed a single test to determine whether these methods would negatively affect the special thread and/or locking mechanisms of the ATB screws and thus interfere with safety, form, fit and function. He does not cite a single FDA or industry standards that Synthes allegedly violated in its testing of the ATB prior to its introduction. He fails to rule out the generally accepted proposition that internal fixation devices such as the ATB fail for non-negligent reasons including but not limited to a patient's failure to achieve bony fusion, surgical technique, a patient's underlying medical condition, post-surgical

activity and a patient's failure to comply with physician instructions. He does not address the evidence from plaintiff's own physician, as well as defense experts, that the ATB screws broke as a result of plaintiff's failure to achieve bony fusion rather than from any defect in the device. Given the foregoing, his opinions and methodology are unreliable, speculative, do not "fit" the facts of the case, are not generally accepted and should be precluded under Daubert.

ARGUMENT

POINT I

SUMMARY JUDGMENT SHOULD BE GRANTED BECAUSE PLAINTIFF CANNOT PROVE PRODUCT DEFECT

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c).

Product liability actions in New Jersey are governed by the New Jersey Products Liability Act ("NJPLA"). N.J.S.A. 2A:58C-1 to -11. The NJPLA governs "action[s] brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1(b)(3).

Here, while plaintiff's complaint asserts causes of action sounding in negligence, breach of warranty, strict product liability and consumer fraud, all such theories are governed by the NJPLA. *See Sinclair v. Merck and Co., Inc.*, 195 N.J. 51, 948 A.2d 587 (2008). To the extent plaintiff intends to pursue an express warranty claim, there is no basis for same because there is no evidence that Synthes made any express warranty to plaintiff.

A. The warnings provided by Synthes with the ATB are adequate as a matter of law.

The NJPLA provides that a manufacturer or seller of a product is liable for harm caused by a product that is "not reasonably fit, suitable or safe for its intended purpose" as a result of a manufacturing defect, a design defect or a failure "to contain adequate warnings or instructions." N.J.S.A. 2A:58C-2. The statute defines what constitutes an adequate warning:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or *in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician*.
>
> [*N.J.S.A.* 2A:58C-4.] [Emphasis added]

The statute thus incorporates the "learned intermediary" doctrine under which a pharmaceutical or medical device manufacturer fulfills its duty to warn the ultimate

user of its product when it supplies physicians with adequate information about the prescription product's dangerous propensities. *Provenzano v. Integrated Genetics*, 22 F.Supp.2d 406 (D.N.J.1998).

In the medical device context, numerous courts have found warnings adequate as a matter of law where the warnings provide information about the known risks associated with a medical device and there is testimony that plaintiff's physician was aware of the risks. For example, in *Fane v. Zimmer*, 927 F.2d 124 (2d Cir. 1991), plaintiff sued the manufacturer of an internal fixation device which had been placed in her hip to aid in fusion following a fracture. Subsequently the fixation device broke due to lack of fusion. The surgeon testified that he was familiar with the risks associated with the use of the device, and stated that the risks were well known. *Id*. at 126. He admitted that breakage of the fixation device is a known medical complication if the bone fracture does not heal and become solid. *Id*. The Court, in granting summary judgment, noted that the manufacturer specifically warned in the package insert of "the risks associated with use of the key-free device and the possibility of breakage or bending of the key-free device when used without external support [i.e. without bone fusion]." *Id*. at 129. Finding the warnings adequate as a matter of law, the Court stated:

> Because the warnings provided specific information on the risks associated with use of the key-free device and Dr. Elting [implanting physician] was fully aware of these risks, we hold as a matter of law that the warnings were adequate. Therefore, we conclude that the Fanes have

> failed to meet their burden of raising a sufficient question of fact concerning the key-free design for the issue to have gone to a jury. . . . Our holding that the warnings provided by Zimmer to Dr. Elting were adequate as a matter of law with respect to the Fanes' claim in strict products liability also resolves their claim of negligent failure to warn. 927 F.2d at 130.

Similarly, in *Adams v. Synthes Spine Co., L.P.*, 298 F.3d 1114 (9th Cir. 2002), the Court held, in a medical device case, that where the Package Insert expressly warns of the precise condition suffered by the patient, the warning is deemed adequate as a matter of law. *See also Cutroneo v. Synthes (U.S.A.)*, 12 A.D.3d 811, 784 N.Y.S.2d 247 (3rd Dep't 2004)(granting summary judgment to Synthes in a spinal rod implantation case where the rod fractured after surgery, finding the warnings adequate as a matter of law.)

Here, it is uncontroverted that the Synthes ATB is a prescription medical device. As such, there are certain unavoidable risks associated with its use. It is legally deemed an "unavoidably unsafe" product that is afforded the protection of Restatement (Second) of Torts § 402A, Comment k. Unavoidably unsafe products are those that "in the present state of human knowledge, are quite incapable of being made safe for their intended ordinary use." Restatement (Second) of Torts § 402A, Comment k (1979).

Each shipment of Synthes product is accompanied by an insert labeled "FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON" (the "Package Insert") that set forth the warnings that apply to all such metallic internal fixation

devices. The Package Insert warned of the very risks complained of by plaintiff. It stated as follows:

- [t]hese implants are intended only to assist healing and **not** intended to replace normal bony structures.
- If there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue.
- Factors such as the patient's weight…,and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant. It is important to note that these implants may break at any time if they are subjected to sufficient stresses.
- These devices can break when subjected to the increased loading associated with delayed union or nonunion.
- Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed.

(See Exhibit L) [Emphasis in original]

As in *Fane*, supra, plaintiff's surgeon, Dr. Levine, testified that he was well aware of the risk of device breakage from lack of bony fusion from his residency training. (Levine Dep., p. 21-22 at Ex. R) He called this basic tenet of orthopedic surgery the "implant race" i.e. the race between bone fusion and implant failure. (Id.) He testified that instrumentation has " a certain life expectancy before they are going to wear out. I don't think the spine is any different in that, I think, it is more the cyclical loading that becomes problematic in this race to get a solid fusion or stability before the potential problems of hardware failing." (Id.) He also testified that "the

concept of cyclical loading and failure of implants and the possibility of failure in situations where bone does not heal, whether it is in the spine or elsewhere is well known, yes." (Id.)

Dr. Levine further testified that complete bony fusion had not occurred in the ten month period following plaintiff's surgery. This allowed enough micromotion to cause a failure of the screws. He testified as follows:

> Q. Is the postsurgical ossification consistent with your view that there was not full union?
>
> A. It is, but frankly, if you have a failure of hardware you kind of have to…believe in absence of any other good explanation that there is a non-union or not a solid fusion that allowed micromotion to occur which fatigued the hardware that broke…
>
> (Levine Dep., p. 94 at Ex. R)

Dr. Joel Spielman, a spine surgeon retained by Synthes, agrees with Dr. Levine concerning the known risk of device failure in the absence of bony fusion. Both physicians agree that plaintiff's failure to achieve bony fusion in the ten month period following his surgery resulted in breakage of the ATB's screws. Dr. Spielman, in his affidavit, states as follows:

> Mr. Jones suffered a delayed fusion/pseudarthrosis as of May 11 2006. This opinion is based on my experience as well as the patient's subsequent clinical course and hardware failure, the radiographs taken in Dr. Levine's office dated April 13, 2006 and May 11, 2006 and subsequent CT scan of May 12, 2006. As a result of delayed/incomplete fusion at the L5-S1 level, the left 5.5 mm Synthes screw in the S1 vertebral body ultimately failed along with the right 5.5. mm Synthes screw in the S1 vertebral body more than a month later.

It is widely acknowledged in orthopedic surgical literature and generally accepted and understood by orthopedic surgeons, that internal fixation devices are intended for temporary fixation, that no internal fixation device will last indefinitely and that failure of an internal fixation device is inevitable in the face of incomplete fusion/pseudarthrosis. Internal fixation devices are subject to cyclical loading, and ultimately will fail in the presence of an incomplete fusion/nonunion.

I am familiar with the Synthes package insert included with the ATB System. The package insert contains appropriate information as to the risks and benefits of the ATB System. [Spielman Aff., ¶ 4-5, 19 at Ex. H]

Dr. Lyle Zardiackas, a metallurgist and biomaterials expert retained by Synthes, offered a similar conclusion. His affidavit states:

It is my opinion to a reasonable degree of engineering certainty that the ATB implanted in Mr. Jones was safe and effective for its intended use. The ATB is meant only as a temporary device for the specific purpose of alignment and stabilization to facilitate healing. It was designed appropriately and produced from suitable materials in order to meet its intended function. The alloy, chosen by Synthes for the ATB, is one which has been scrutinized by ASTM and the scientific community and deemed to be safe and effective.

It is further my opinion to a reasonable degree of engineering certainty that fracture of the ATB screw occurred due to delayed union or non-union of the bone which is evidenced by the medical reports. It did not occur as a function of a defect in the screw. The function of a fixation device is to align the bone and to promote proper healing. It is not designed to be a permanent replacement for bone, (i.e., it is not a prosthesis). Therefore, the implant will fracture if subjected to cyclical loading of sufficient duration at sufficient stress levels. Even though the ATB is manufactured from implant quality Ti-6AI-7Nb, it is not able to withstand as great a repetitive cyclical load without fracture as fully healed bone. I base these opinions upon my education, experience with orthopaedic implants, and review of the documentation in this case.

> Based on my analysis, the Synthes screws were fit for their intended purpose and were not defective in design or manufacture. (Zardiackas Aff. ¶ 20-22 at Ex. I)

As in *Fane*, supra, Synthes has demonstrated 1) that the warnings provided with the ATB were adequate; 2) that the very event experienced by plaintiff, breakage of the device from a lack of fusion, was warned about in the Package Insert and 3) that plaintiff's surgeon was aware of the risks of the ATB as set forth in its Package Insert. Accordingly, plaintiff cannot establish failure to warn and all such claims should be dismissed.

B. Plaintiff has no reliable evidence of a manufacturing or design defect.

The NJPLA Section 2A:58C-2 provides that:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

When a product liability case is based on a proposed alternative design, it is well settled that the failure to test the alternative design for either feasibility or safety can result in summary judgment. For example, in *Oddi v. Ford Motor Company*, 234 F.3d 136 (3d Cir. 2000), the Court granted summary judgment in a crashworthiness

case in favor of a truck manufacturer based on plaintiff's expert's failure to test certain alternative design theories which the expert claimed would have made the truck safer. The Court reasoned that, since the expert failed to test his hypotheses, there was "no way of knowing if his suggested alternatives would better protect the cab's occupant, of if the suggested modifications were practical." *Id*. at 159; *see also*, *Kolokowski v. Crown Equipment Corporation*, 2009 WL 2857957 (D.N.J. 2009)(holding plaintiff's expert's testimony on proposed alternative designs inadmissible because the expert failed to perform any testing.); *see also Milanowicz v. The Raymond Corporation*, 148 F.Supp.2d 525 (D.N.J. 2001)(summary judgment granted in favor of lift manufacturer based on plaintiff's expert's failure to provide "good grounds" for his opinion due to the lack of testing and validation of his theories.)

Here, plaintiff's expert Mr. Lieberman suggests that Synthes should have used certain alternative design/manufacturing methods called shot peening, gray anodization and dye penetrant testing, which he opines would have improved the ATB's fatigue life and/or uncovered flaws in the metal used to manufacture the ATB. Plaintiff's expert's theories, as to shot peening and gray anodization, are speculative because Mr. Lieberman has not performed any testing to validate that the methods he recommends would improve fatigue life as he claims without compromising the safety, form, fit and function of the ATB. His dye penetrant testing theory lacks reliable support because Mr. Lieberman never tested the process to assure

biocompatibility and safety with respect to its use with surgical implants intended for human use.

i. Shot Peening: Mr. Lieberman's first alternative manufacturing method is called "shot peening." According to Mr. Lieberman, shot peening is a process "in which the surface of a component is bombarded with small spherical particles of metal, glass, or ceramic. Each piece of shot striking the metal surface acts as a tiny peening hammer imparting to the surface a small indentation or dimple. To create this dimple, the surface the layer must yield in tension. Below the surface, the bulk metal in attempting to regain it original shape generates a compressive stress in the cold worked surface." (Lieberman Sept. 2009 Report at p. 3 at Ex. G)

Mr. Lieberman testified that his alternative design plan for shot peening exists solely in his mind and has not been committed to paper. (Lieberman Dep., p. 77-78 at Ex. S). He further testified that, because he has not tested shot peening on an exemplar ATB screw or any other cancellous bone screw, he cannot state to what extent it would in fact have improved the fatigue life of the ATB screw, facilitated fusion, and/or improved the surgical outcome for Mr. Jones. (Lieberman Dep., p. 124)

Mr. Lieberman also has not tested whether shot peening the screw, i.e. making it stronger, would adversely affect its intended function, as an aid to bone growth and fusion, through a process known as "stress shielding". (Lieberman Dep., p. 182-183 at Ex. S) As attested to by Dr. Zardiackas, stress shielding is a well-known concept

in the field of internal fixation devices. Dr. Zardiackas states "if the construct is too large or too strong, it may limit the load bearing of the bone, a process called stress shielding. This would impede bone healing and fusion and thus be contrary to the goal of fusion surgery." (Zardiackas Aff. ¶ 8 at Ex. I) Dr. Spielman also stated that "a surgeon does not want a device that will shield the graft site from loading. This is called stress shielding where the device, rather than the graft site, handles the majority of the load that a person places on his spine. It is generally accepted that stress shielding inhibits rather than aids fusion." (Spielman Aff. ¶ 14 at Ex. H)

Demonstrating Mr. Lieberman's lack of education, training and experience in the field of internal fixation devices and spinal fusion surgery, he testified that he never heard of the concept of stress shielding. Nevertheless, he declared, without citation or testing, that he did not believe there would be any negative impact on fusion if the medical device permanently took the entire load and no load was transferred to the bones. (Lieberman Dep., p. 121, 179 at Ex. S)

Mr. Lieberman has not validated whether a cancellous bone screw, like the screws used in the ATB, could be shot peened without damaging the specially-designed threads of the screw which are crucial for the screw's intended purpose of obtaining purchase within the bone. (Lieberman Dep., p. 221-222, 265-267 at Ex. S) In fact, as attested to by Dr. Zardiackas, shot peening has a high potential to cause such damage. He writes that the process has never been validated or peer-reviewed for use with cancellous bone screws. Dr. Zardiackas is not aware of any

manufacturer which uses the process for cancellous bone screws. Dr. Zardiackas states as follows:

> To my knowledge, no implant manufacturer uses shot peening for the manufacture of cancellous bone screws. Moreover, to my knowledge, the process of shot peening bone screws has not been subjected to the testing required for validation nor has it been peer reviewed for this application. The primary reason for not using shot peening for cancellous bone screws is the need to maintain the screw thread profile. The cancellous screw design used for the ATB system has a deep thread profile with very sharp edges at the crest of the thread. The deep threads are necessary to provide purchase in the cancellous bone, and the sharp edges allow the ATB screw to cut the more dense cortical bone as well as the cancellous bone. These attributes are further required since the ATB screw is a unicortical screw, i.e., the screw does not penetrate the far cortex of the vertebral body to prevent the possibility of screw impingement on the spinal cord. Additionally, the ATB screw has a locking thread at the head which engages the threaded holes of the ATB plate to lock the screw and prevent the screw from backing out of the plate and the bone. As a result of these requirements, damage to either of the threads would compromise the intended function of the ATB screws. Shot peening has a very high potential to damage either or both of the threads during its use. (Zardiackas Aff., p. ¶ 13 at Ex. I)

In lieu of testing and validation, Mr. Lieberman cites, as support for his shot peening theory, a Spring 2008 article published in a magazine called "The Shot Peener." (Ex. W) The article references a company, Medtronic, that was evaluating in 2008, years after the ATB was designed, introduced and implanted in plaintiff, the use of shot peening for certain of its surgical screws, although, not cancellous bone screws of the type used in the ATB.

The article, which was neither peer-reviewed nor published in a peer-reviewed journal, provides insufficient support for Mr. Lieberman's opinions. First, Mr.

Lieberman testified at deposition that the screws referenced in the article were made of a different material than the ATB screws. (Lieberman Dep., p. 89 at Ex. S) Second, the article states that Medtronic was still validating the process to try to meet FDA requirements. (Ex. W, p. 2) Third, Mr. Lieberman testified that he was not aware of a single company making spine screws who were shot peening the screws in 2005 when plaintiff's surgery took place. (Lieberman Dep., p. 217 at Ex. S)

Dr. Zardiackas reviewed the article on Synthes' behalf. He states as follows:

> As to the article submitted by Mr. Lieberman, *Validating the Shot Peening Process*, this article was taken from a magazine not a peer reviewed scientific journal. Of greater importance, is the fact that this article only proposes that Medtronic (Sofamor Danek Group) was evaluating the possibility of using the process for spine screw applications as described in the article. Additionally the article was published in 2008, many years after the design, manufacture and implantation of the ATB screws at issue. While Mr. Lieberman suggests that Medtronic is using said new testing method, the article states that they are only performing human simulation testing to satisfy the FDA. To my knowledge, neither Medtronic nor any other implant manufacturer uses shot peening for cancellous bone screws, and I am not aware of any published peer reviewed research papers validating the process for implantable screws by Medtronic Sofamor Danek or any other implant manufacturer. (Zardiackas Aff. ¶ 14 at Ex. I)

Given the foregoing, Mr. Lieberman's opinion that the ATB was defective because it was not shot peened should be excluded because it has no scientific support and has not been validated to see if it would 1) improve fatigue life as claimed by Mr. Lieberman, 2) have improved the surgical outcome or achieved fusion in the case of plaintiff or others similarly situated, or 3) for feasibility, efficacy

and safety. His opinion is speculative and unreliable, and provides no basis to deny Synthes' summary judgment motion.

ii. Gray Anodization: Mr. Lieberman, in his September 2009 report, opines that Synthes should have investigated the use of gray anodization. This is a process that imparts a gray color to the surface of a device, imparts increased lubricity, and increases the fatigue strength of titanium. (Zardiackas Aff. ¶17 at Ex. I)

As with his shot peening theory, Mr. Lieberman has done no testing to validate whether the use of gray anodization would be feasible, safe or improve the fatigue life of cancellous bone screws of the type used in the ATB. (Lieberman Dep., p. 274, 284)

Mr. Lieberman cites as support an article entitled *Surface Treatments of Titanium Implants*. He testified that he found this article on the internet, does not know anything about the professional or academic background of its authors, and does not know if the article was peer reviewed. (Lieberman Dep., p. 255-256 at Ex. S)

Mr. Lieberman failed to validate whether the use of gray anodization compromises the function of the ATB or the safety benefit that color-coding the screws provides in avoiding sizing errors during surgery. As attested to by Dr. Zardiackas, should Synthes impart a gray color to all of its surgical screws via anodization as suggested by Mr. Lieberman, it would interfere with Synthes' ability to color code its implants and thus increase the risk of sizing errors. It could also

negatively affect the holding power of the screws in bone because of the increased lubricity caused by anodization. Dr. Zardiackas states as follows:

> [Gray anodization], however, eliminates the ability to color code implants using anodization to reduce the possibility of sizing errors during surgery. Since the anodization process results in different colors to the surface based upon oxide thickness, there is no compromise related to function or biocompatibility and color coding is achieved. In the case of ATB screws, color coding to reduce the risk of sizing errors is particularly important since the screws are designed to have unicortical purchase thus eliminating impingement on the spinal cord which can result in irreversible damage and paralyzation. Moreover, using gray anodization as suggested by Mr. Lieberman, is known to increase surface lubricity which could be undesirable for a screw meant to maintain purchase and enhance the potential for bone fusion. (Zardiackas Aff. ¶ 17 at Ex. I)

Given the foregoing, Mr. Lieberman's opinion that the ATB was defective because it did not undergo gray anodization should be excluded because it has no scientific support and has not been validated to see if it would 1) improve fatigue life as claimed by Mr. Lieberman, 2) have improved the surgical outcome or achieved fusion in the case of plaintiff or others similarly situated, or 3) for feasibility, efficacy and safety. His opinion is speculative and unreliable and provides no basis to deny Synthes' summary judgment motion.

iii. Dye Penetrant Inspection: As a final alternative manufacturing/design method, Mr. Lieberman suggests that Synthes should have used dye penetrants as part of its inspection process to look for surface flaws in the material it uses to manufacture the screws used in the ATB. The process involves using dye penetrants

to detect the presence of *surface* defects on forged and cast medical devices which are much larger and have less tortuous surface profiles than ATB screws.

Mr. Lieberman has no reliable support for the application of this method with implants intended for use in humans. His sole support consists of an article he found on Wikepedia which, according to their website, "is a free encyclopedia that anyone can edit." (Lieberman Dep., p. 223 at Ex. S; http://en.wikipedia.org) Clearly, this is not the type of scientific material that a reliable opinion is built upon. Mr. Lieberman further testified that he is not aware that dye penetrant inspection has ever been used for surgical screws. (Lieberman Dep., p. 223) He is not aware of any company that makes screws for use in spinal fusion that performs dye penetrant inspection of the screws. (Lieberman Dep., p. 223, 229) He further testified that ultrasonic testing, which is performed by Synthes' titanium suppliers, looks at not just the surface, like a dye penetrant inspection does, but the totality of the metal. (Lieberman Dep., p. 225, 277)

Mr. Lieberman has performed no analysis as to whether it is feasible or safe to use dye penetrants on a screw meant for implantation in the human body. (Lieberman Dep., p. 238 at Ex. S) He testified that he has not done any testing to determine whether you can dye penetrant test the ATB screws and then completely remove the chemical residue from the screws prior to implantation. (Lieberman Dep., p 268) He is not aware whether the solvents used in dye penetrant testing are biocompatible with humans. (Lieberman Dep., p. 271-272) He has not analyzed

whether conducting a dye penetrant inspection of every screw manufactured by Synthes is feasible from a cost perspective, or even beneficial, given that Synthes' suppliers perform the more complete ultrasonic inspection. (Lieberman Dep., p. 238)

In fact, dye penetrant testing is neither feasible nor safe for surgical screws of the type used in the ATB. Dr. Zardiackas states as follows:

> Mr. Lieberman also suggests that Synthes should have used dye penetrants as part of its inspection process to look for cracks in the material it uses to manufacture the screws used in the ATB. Dye penetrants are generally used to detect the presence of surface defects, including cracks on forged and cast medical devices which are much larger and have less tortuous surface profiles. The major drawback with the use of this process is the difficulty of cleaning the surface of the device after examination. Any manufacturer of implantable medical devices must follow the principle of "Do no harm". In light of this principle, no substance which is not biocompatible or might interfere with the sterilization process can remain on the surface. The ATB screw at issue not only has threaded areas which must be clean and sterile but also the head and hexagonal slot for the screw driver must be clean and sterile. The presence of any dye penetrants which may be trapped especially at the line intersection between the walls and base of the hexagonal area is not acceptable and poses an unacceptable risk to the patient. To my knowledge, the use of dye penetrants for this particular application has never been tested, validated, nor peer reviewed as an acceptable technique for the inspection of cancellous bone screws.
>
> It is also important to note that the practice of the titanium suppliers, who provide titanium to Synthes, is to provide certified titanium and titanium alloy bar stock for the production of screws for implantation and to perform x-ray or ultrasonic inspection of the bar stock prior to certification and shipment to implant manufacturers including Synthes. This process essentially eliminates the possibility of defects, including cracks in the wrought bar from which the screws are machined. It is

highly improbable that a crack could arise during the machining process. (Zardiackas Aff. ¶ 15-16 at Ex. I)

Given the foregoing, Mr. Lieberman's opinion that Synthes should have investigated the use of dye penetrant inspection of its ATB screws has no reliable scientific support and has not been tested or validated to determine whether it could be safely used on implants intended for human use, whether it is feasible from a cost perspective or whether it is beneficial or necessary given that the titanium used by Synthes undergoes the more complete ultrasonic inspection.

C. Mr. Lieberman's criticism of Synthes' testing of the ATB is without basis.

As a catchall theory, plaintiff's expert submits that Synthes did not adequately test the ATB to determine its fatigue life. Mr. Lieberman asserts that Synthes' testing should have accounted for all the normal variables, body weight, patient movement, variables in surgical procedure, that the ATB would encounter in a patient. (See Lieberman June 2009 report at Ex. F)

Mr. Lieberman has no support for this claim. The ATB was approved for use by the FDA. (See Ex. O) Synthes tested the ATB as per industry and FDA standards by running both a static axial test and a dynamic axial compression/tension fatigue test to 10,000,000 cycles. (See ATB test results at Ex. O- SYNTH001738 – SYNTH 1742; Deposition of Benjamin Barrall, p. 60-62 at Ex. T) Since the ATB did not fail at 10,000,000 cycles, the test is stopped, and the device is not tested to breakage. Mr.

Lieberman cites no federal or industry standards which require that Synthes run the test to failure or that it run any additional tests of fatigue life.

Moreover, despite Mr. Lieberman's claim that Synthes should have done the impossible by designing a test that could account for all variables in patient weight, patient movement, surgical technique, patient compliance with post surgical instructions, a patient's underlying medical conditions and differences in the rate of healing, he testified that he was not aware of any test that could account for all the variables that an internal fixation device encounters after implantation in the body. (Lieberman Dep., p. 158-159 at Ex. S) Dr. Zardiackas agrees:

> It is also not possible to determine how long a device designed for this type of application will last either as a function of time or as a number of cycles because the load for each cycle imposed on the implant by an individual cannot be determined. The reason for this dilemma is that no two patients have the same anatomy or physiology, nor do they impose the same variable load spectrum on a device which has been implanted. (Zardiackas Aff. ¶ 4 at Ex. I)

Given plaintiff's failure to cite a single government or industry standard that Synthes allegedly violated in its testing of the ATB prior to its introduction, plaintiff's vague and unsupported criticism of Synthes' testing of the ATB provides an insufficient basis to deny Synthes summary judgment. *See Milanowicz v. The Raymond Corporation*, 148 F.Supp.2d 525 (D.N.J. 2001)(holding that an expert's failure to cite relevant federal or industry standards regarding a product's design can be used as a criteria for precluding the testimony as unreliable.)

Plaintiff has failed to come forth with reliable support for his claim that the Synthes ATB suffered from a defect in manufacturing or design or that its warnings were inadequate. Given the foregoing, summary judgment should be granted in favor of Synthes.

POINT II

SYNTHES SHOULD BE GRANTED SUMMARY JUDGMENT BECAUSE PLAINTIFF CANNOT PROVE CAUSATION WITHOUT AN EXPERT KNOWLEDGEABLE IN MEDICAL ISSUES

It is well settled that a plaintiff, in order to set forth a prima facie case under New Jersey's Product Liability Act, must establish that a defect in the product caused him to sustain an injury. *See Cruz-Mendez v. ISU/Insurance Services*, 156 N.J. 556 (1999). Further, where the allegedly defective product involves a complex instrumentality, a plaintiff is required to provide expert testimony. *Kolowlowski v. Crown Equipment Corporation*, 2009 WL 2857957 * at 4 (D.N.J. 2009).

In the medical device context, courts have granted summary judgment where plaintiff failed to retain a medical expert to provide causation testimony. For example, in a case directly on point, *Fane v. Zimmer*, 927 F.2d 124 (2d Cir. 1991), the Court rejected the medical causation testimony of a metallurgist in a case alleging medical injuries from a broken orthopedic implant. In *Fane*, plaintiff sued the manufacturer of an internal fixation device which had been placed in her hip to aid in fusion following a fracture. Subsequently the fixation device broke due to lack of fusion. The implanting surgeon testified that Ms. Fane's bone had not healed

sufficiently to prevent a refracture. *Id*. at 126-27. Plaintiff's expert metallurgist was prepared to testify that the broken fixation device was a substantial factor in causing the bone to refracture. *Id*. at 127. At trial, the district court refused to allow the metallurgist to testify on causation and granted a directed verdict to defendant, holding that plaintiff had failed to meet her burden of proof. *Id.* at 127-28. The Second Circuit affirmed:

> The district court properly did not allow the metallurgist to testify to whether the breakage in the device caused the bone fracture, finding it was beyond his area of expertise. . .
>
> * * *
>
> What causes a bone to fracture, however, is a medical question. In many instances, it might be a matter within the experience and observation of the ordinary juryman. This case, however, is different. Mrs. Fane suffered a complex injury. Implantation of the key-free device involved complicated surgery. Additionally, the key-free device implanted in Mrs. Fane was not one with which an ordinary person would come in contact. The issue of causation in such a complicated medical case, therefore, was beyond the sphere of the ordinary juryman and required expert testimony.
>
> * * *
>
> Absent competent medical expert testimony on the issue of causation, the Fanes could not prove the elements of a cause of action based in strict products liability or negligence. *Id*. at 131-132.

See also, Mead v. Synthes Spine Company, 2007 WL 1530114 (E.D.Mo. 2007)(dismissing complaint because plaintiff could not establish that the fracture of the screws was a result of defect in device); *see also Menges v. Depuy Motech, Inc.*, 61 F.Supp.2d 817 (N.D.Ind. 1999)(holding that a physician, not trained in neurology,

neurosurgery, spinal instrumentation, or general surgery, was not qualified to testify as to medical causation in a spinal fusion case.)

Here, plaintiff cannot establish medical causation, i.e. that the breakage of two of the ATB's screws caused him to sustain injury, because he failed to retain an expert who can address medical issues. His only expert, Warren Lieberman, has no education, experience or training in medicine or spinal fusion surgery. He testified that he has no idea what is causing plaintiff's current back complaints or whether they are related to breakage of the screws. (Lieberman Dep., p. 70, 133 at Ex. S)

In contrast, plaintiff's surgeon, Dr. Levine, and Dr. Spielman, a spine surgeon retained by Synthes, testified or attested to the fact that the broken screws were not causing plaintiff's current complaints; that plaintiff had documented disc disease at other levels of his spine that were not treated during the July 2005 surgery; and that plaintiff's current symptoms are different than his pre-surgical complaints and were caused from the other damaged sections of his spine. (See SYNTH000257 and 000415-418 at Ex. P; Levine Dep., p. 58, 79 at Ex. R; Spielman Aff. ¶ 6, 8, 17-18, 20-22 at Ex. H)

Both Dr. Levine and Dr. Spielman testified or attested to the fact that the purpose of the ATB was to provide supplemental support for the interbody device and graft material that was inserted in place of the removed disc. (Levine Dep., p. 19 at Ex. R; Spielman Aff. ¶ 13 at Ex. H) The post-surgical medical records, and Dr. Levine's testimony, confirm that the Globus interbody device as well as the ATB

remained in alignment before and after the breakage of the screws. (See Levine Dep., p. 92-93 at Ex. R, SYNTH000232-000234; 000238 at Ex. P) Moreover, Dr. Levine testified the instrumentation, including the broken Synthes' screws which remain, are not impinging on any of plaintiff's nerves and are unrelated to plaintiff's current complaints of pain. He testified "as far as the hardware in his spine, the hardware was nowhere in the vicinity of the nerves that would go down the left lower extremity to cause those symptoms." (Levine Dep., p. 79)

The evidence is also uncontroverted that the limited goals of the surgery were achieved. Prior to surgery, plaintiff had severe and debilitating back pain radiating down his right leg which he described as "break-down-crying" pain. (Jones Dep., p. 125 at Ex. Q) He was on restricted duty at work. He was having difficulty performing daily activities. (SYNTH000259 at Ex. P) Dr. Levine testified that the goal of surgery was a hoped for 50% reduction, rather than elimination, of plaintiff's lower back pain. (Levine Dep., p. 42 at Ex. R) Dr. Levine specifically warned plaintiff that, since he was only operating on the L5-S1 section of his spine, plaintiff may still experience back pain after surgery because the other diseased sections of his spine were left untreated. (Levine Dep., p. 58) Plaintiff testified that he was aware that the surgery was only intended to treat the L5-S1 level and that the goal was to alleviate, rather than eliminate, his pain. (Jones Dep., p. 238-239) Plaintiff testified that after surgery his pain "was different, but it's not as bad as before the first surgery." (Jones Dep., p. 218) He rated his pain as 3 out of 10 after the surgery.

Before the surgery, he rated his pain at either 7 out of 10 or 10 out of 10 with 10 being most severe. (Jones Dep., p. 212-218) Thus, by plaintiff's own testimony, he was aware of the limited goals of the surgery and said goals were achieved.

Since plaintiff has failed to retain an expert who can address medical causation, he cannot contest the evidence that 1) plaintiff's failure to fuse caused breakage of the ATB's screws; 2) that the failure to fuse necessitated revision surgery; 3) that plaintiff had pre-existing disc disease at other levels of his spine that were not treated during his surgery; 4) that plaintiff's current complaints are not related to the breakage of the ATB's screws and; 5) that the limited goals of the surgery were achieved. Accordingly, he cannot prove causation, an essential element under the NJPLA, thus requiring summary judgment in favor of Synthes.

POINT III

PLAINTIFF'S EXPERT DOES NOT MEET THE DAUBERT STANDARD AND HIS OPINIONS SHOULD BE PRECLUDED

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, states that "a witness qualified as an expert…may testify thereto…if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. In *Kumho Tire Co., Ltd. v. Carmichael*, 526

[3] Mr. Lieberman testified that, since the ATB screws remain in plaintiff, he has no basis to state that a surface flaw was present.

U.S. 137, 149 (1999) (citing *Daubert*, 509 U.S. at 592), the Court stated that "Federal Rules 702 and 703 grant expert witnesses testimonial latitude unavailable to other witnesses on the 'assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.'" Accordingly, the trial court must act as a "gatekeeper" "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152.

A. Mr. Lieberman is not qualified to offer testimony on internal fixation devices, fusion surgery or biomaterials.

Rule 702 of the Federal Rules of Evidence, which governs the admission of expert testimony, provides that only "a witness qualified as an expert by knowledge, skill, experience, training, or education" may give expert testimony on an issue that requires scientific, technical or other specialized knowledge. Thus, before addressing the issue of whether testimony is admissible, the court must first determine that the individual, whose testimony is proffered, is an expert in the requisite scientific field. *Daubert v. Merrell Dow Pharmaceutical (Daubert II)*, 43 F.3d 1311 (9th Cir. 1995).

In determining whether a witness is qualified to testify as an expert, the court should undertake a two-step inquiry: First, the court "should determine whether the proffered expert has minimal educational or experiential qualifications in a field that is relevant to a subject which will assist the trier of fact;" second, the court "should

further compare the expert's area of expertise with the particular opinion the expert seeks to offer [and permit t]he expert ... to testify only if the expert's particular expertise, however acquired, enables the expert to give an opinion that is capable of assisting the trier of fact." *See, Zwillinger v. Garfield Slope Housing Corp.*, 1998 WL 623589 (E.D.N.Y. 1998) quoting *Federal Judicial Center, Reference Manual on Scientific Evidence* 55-56 (1994).

In the medical device context, numerous courts have excluded expert testimony based on an expert's lack of education, experience and qualifications in this specialized field of medicine. For example, in *Muller v. Synthes Corp.*, 2001 WL 521390 (N.D.Ill. 2001), plaintiff alleged that a cervical neck plate used to aid healing after cervical spine fusion surgery was defective because it was found to have fractured on two occasions after it was implanted in plaintiff. Plaintiff retained a metallurgist and a bioengineer to testify that the device fractured as a result of faulty design. *Id*. at 3. In precluding the experts, the Court found that the experts did not have any experience with medical implants, cervical locking plate devices, issues relating to fusion of the cervical spine, procedures for implanting a cervical locking plate, the expectations of medical science as to the range of stresses the device will be exposed to, how long the device is expected to function under these stresses, and whether the device is expected to continue functioning if the patient experiences slow bone healing i.e. lack of fusion. *Id.* The Court stated that "without knowledge of such information, it is unlikely that any testimony the witnesses might offer about whether

the [device] is a defective design could be either relevant or reliable." *Id*. at 5; *see also Krueger v. Johnson and Johnson Professional, Inc*., 2002 WL 34371190 (S.D. Iowa 2002)(precluding expert from testifying in a case involving a cervical plate because the expert was not a medical doctor or engineer, had no formal training in biomechanical, biomedical or health care fields and had not authored any professional publications on those topics).

It is respectfully submitted that Mr. Lieberman should be precluded from offering expert testimony because he lacks education, qualifications and/or experience in orthopedic internal fixation devices, spinal fusion surgery, or biomaterials. Mr. Lieberman is a metallurgical engineer who spent thirty-four years of his career at the Boeing Company responsible for airplane design. (See Lieberman CV at Ex. E) While Mr. Lieberman seeks to offer opinions on fusion surgery, biomaterials, and internal fixation devices, he has no discernable education, training or experience in these areas. He is neither a physician nor a spine surgeon. (Lieberman Dep., p. 12 at Ex. S) He has never consulted or testified before on any implantable surgical device case. (Id. at 29) He does not have any education, training or experience in the field of medical devices. (Id. at 35) He has never been employed by or consulted for a company that designs, manufactures or tests medical devices. (Id. at 35) He has never designed a medical device. (Id. at 35-36) He has never conducted a clinical trial of a medical device. (Id. at 37) He is not a member of any professional organizations that deal with medical devices. (Id. at 36) He has

never published any scientific papers with respect to medical devices. (Id. at 36) He has never studied, and has no formal training in, the field of biomechanics. (Id. at 8, 21) He has never studied the application of metal in an implantable surgical device. (Id. at 9) He has no formal training in orthopedics and has never observed a surgical procedure. (Id. at 20) He has never taught or given any lectures on spinal surgery, orthopedic surgery, medical devices, biomechanics or the effect of blood, body tissue and bone on implantable surgical devices. (Id. at 22-23) He has never written any peer reviewed articles on these topics. (Id. at 23) Mr. Lieberman has no expertise in testing implantable medical devices or analyzing the cause of the breakage of a surgical screw. (Id. at p. 147, 150)

Although Mr. Lieberman is proffered to offer quasi-medical opinion testimony concerning the process of spinal fusion and what role the ATB plays in that process, he has no training, education or experience in this area. His June 17, 2009 and September 24, 2009 reports are rife with basic errors which reveal his lack of knowledge in this area. For example, in the Opinions section of his June 2009 report, he writes that the ATB screw "was implanted in the S1 disc" and at page 2 of his September 2009 report, he writes that the ATB is placed between the two discs. (Id.) In fact, the ATB screws are implanted in the vertebrae not the discs and the ATB is placed between the two vertebrae not between the discs. (Levine Dep., p. 17 at Ex. R; see also July 2005 Operative Report at Ex. J) Mr. Lieberman testified that he needed to "look up on the internet to understand the structure of the spine, just to get

a feel exactly where was this implant done. So I did a little bit of homework on that, just to basically see a sketch of the spine and how it's identified." (Lieberman Dep., p. 38 at Ex. S) He further testified that he has no expertise with respect to the steps a surgeon takes to implant a spinal fusion device. (Id. at 39) He has no expertise with respect to how spinal fusion surgery is supposed to reduce a patient's pain. (Id. at 53-54)

Mr. Lieberman never heard of a basic tenet of fusion surgery i.e. the "race to fusion." (Lieberman Dep., p. 59-62 at Ex. S) He has never studied medical journals, orthopedic textbooks or other materials about the race to fusion. (Id. at 59-62)

Mr. Lieberman also never heard of the term stress shielding, a key concept in designing internal fixation devices. (Lieberman Dep., p. 64 at Ex. S) As set forth under Point II, stress shielding is a concept that in designing a medical device to aid fusion you do not want to make the device so strong that the load will be borne entirely by the device rather than the bones. (Spielman Aff., ¶ 14 at Ex. H; Zardiackas Aff. ¶ 8 at Ex. I) Mr. Lieberman's lack of familiarity with this basic concept demonstrates that he is testifying out of his field of expertise.

Mr. Lieberman also demonstrated a lack of knowledge of the purpose of the interbody device/spacer that was used by Dr. Levine. Dr. Levine testified and Dr. Spielman attested to the fact that the interbody device/spacer and the graft material, rather than the ATB which acts as supplemental support, are the key parts in achieving fusion. (Levine Dep., p. 16-20 at Ex. R; Spielman Aff., ¶ 8 at Ex. H) Mr.

Lieberman mistakenly states that the ATB, rather than the interbody device/spacer, is the main support for the fusion process. (Lieberman Dep., p. 291, 332 at Ex. S) As testified to by Dr. Levine and attested to by Dr. Spielman, this is demonstrably false.

Given Mr. Lieberman's lack of education, training and experience in the fields of internal fixation devices, biomaterials, orthopedics and fusion surgery, his opinions are unreliable, would be of no assistance to the trier of fact and should be excluded.

B. Mr. Lieberman's opinions are not based on reliable methodology.

In *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786, the Supreme Court set forth a number of factors that the Courts should consider in determining whether an opinion is reliable. These factors include (1) whether a theory or technique "can be (and has been) tested," *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786; (2) "whether the theory or technique has been subjected to peer review and publication," *Id.;* (3) a technique's "known or potential rate of error," and "the existence and maintenance of standards controlling the technique's operation," *Id.* at 594, 113 S.Ct. 2786; and (4) whether a particular technique or theory has gained "general acceptance" in the relevant scientific community. *Id.* When an expert opinion is based on data or a methodology that are inadequate to support the conclusions reached, said opinions must be excluded. See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-42, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997).

i. Mr. Lieberman's alternative design methods have not been tested.

One of the principle criteria for determining the reliability of an expert's opinion is whether the opinion has been subjected to testing. *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786. As stated by the Court in *Milanowicz v. The Raymond Corporation*, 148 F.Supp.2d 525 (D.N.J. 2001), "this testing may involve only the allegedly defective design, or, in alternative design cases, could address the proposed alternative as well. Regardless, testing applies scientific or technical principles to the subject at issue. Before a court can evaluate the reliability of an expert's methodology, the expert must employ one."

Applying these principles to internal fixation device cases, courts have rejected expert testimony based on an expert's failure to test. For example, in a case directly on point, *Phelan v. Synthes (U.S.A.)*, 35 Fed.Appx. 102 (4th Cir. 2002), plaintiff filed suit claiming that a "tibial nail" implanted in her leg following a tibial fracture was defective because the tibial nail had broken months after the surgery took place. Plaintiff's expert, a "biomedical engineer," intended to testify that the tibial nail was defective. The Court excluded the testimony finding that "he did not conduct any tests nor perform any calculations regarding the nail in question." *Id.* at 107.

Similarly, in *Krueger v. Johnson and Johnson Professional*, 2002 WL 34371190 (S.D.Iowa 2002), plaintiff filed suit against a medical device manufacturer claiming that bone screws used to hold a cervical plate during fusion surgery were defective because the screws broke following surgery. Plaintiff's expert intended to

testify that a design or manufacturing defect with the screws caused plaintiff's injury. The expert, however, never evaluated the plate system explanted from plaintiff nor conducted testing. The Court excluded the expert holding that his opinions were not based on "good grounds." *Id*. at 4.

Here, plaintiff's expert, Mr. Lieberman, suggests that Synthes should have used certain alternative manufacturing methods called shot peening and gray anodization, which he speculates would have improved the ATB's fatigue life. He also suggests that Synthes should have used an inspection method called dye penetrant inspection which he claims may have revealed a surface flaw in the ATB's screws if one was present.[3] As set forth above under Point I, Mr. Lieberman's opinion that the ATB was defective because it was not shot peened or gray anodized should be excluded because it has no scientific support and has not been validated to see if it would 1) improve fatigue life as claimed by Mr. Lieberman, 2) have improved the surgical outcome or achieved fusion in the case of plaintiff or 3) for feasibility, efficacy and safety. Similarly, as addressed in Point I, his opinion that Synthes should have investigated the use of dye penetrant inspection of its ATB screws should be excluded because it has no reliable scientific support and has not been tested or validated to determine whether it could be safely used on implants intended for human use, is feasible from a cost perspective or even beneficial given that the titanium used by Synthes undergoes the more complete ultrasonic inspection. Finally, as addressed in Point I, plaintiff's vague and unsupported criticism of

Synthes' testing of the ATB, without citation to any government or industry standards that Synthes allegedly violated, provides an insufficient basis to deny Synthes summary judgment.

In sum, plaintiff has failed to provide any reliable support for his claim that the Synthes ATB suffered from a defect in warnings, manufacturing or design. Mr. Lieberman's opinions provide no such support and should be excluded because they are not based on reliable methodology as required under Rule 702 and Daubert.

ii. Mr. Lieberman's opinions do not "fit" the facts of the case.

For expert testimony to "fit," the testimony must have a valid "connection to the pertinent inquiry" and be "sufficiently tied to the facts of the case so that it will aid the jury in resolving a factual dispute." *Daubert* at 591-592, 113 S.Ct. 2786. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-42, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)

Here, Mr. Lieberman's opinion does not fit the facts because he fails to address, let alone rule out, the uncontested medical evidence and testimony establishing that the breakage of the ATB's screws resulted from plaintiff's failure to achieve fusion rather than from any defect of the ATB. He testified that he cannot even identify what factors, other than manufacturing defect, may cause a surgical

screw to break. Because it is outside of his area of expertise, he cannot opine on whether surgical technique, rate of bony healing, individual body characteristics, etc. can cause a failure to fuse and subsequent screw breakage. (Lieberman Dep., p. 293-294 at Ex. S) Given his lack of expertise, Mr. Lieberman cannot reliably tie his opinions to the facts of the case.

Mr. Lieberman's opinions do not account for the generally accepted risk in spinal fusion surgery that a certain percentage of patients will not achieve bony fusion. (*See* Spielman Aff. ¶ 5 at Ex. H) His opinion ignores the fact that it is generally accepted in the fields of metallic internal fixation devices, biomaterials, orthopedics and fusion surgery that internal fixation devices are intended solely for temporary fixation, that no internal fixation device will last indefinitely and that internal fixation devices are subject to cyclical loading, and ultimately will fail in the presence of an incomplete fusion/nonunion. *Id.*

The general acceptance of the "implant race" is evidenced in numerous orthopedic textbooks and biomaterial literature. (Exs. U and V) These textbooks identify numerous non-defective reasons for device breakage including loosening of the implant due to bone resorption; delayed union or nonunion due to biological considerations; secondary trauma at or near the original fracture site; overloading of the implant by the patient; inadequate reduction or alignment; improper implant handling during placement; implant degradation due to biological considerations; and implant wear. (See Ex. U, p. 123 and Ex. V, p. 672)

The concept is also discussed in the Package Insert that accompanied each shipment of Synthes internal fixation devices. The Package Insert specifically warned about the risks of device breakage from nonunion (lack of fusion). (See Ex. L) The "implant race" is documented in the testimony of Dr. Levine, plaintiff's spine surgeon, who testified that he learned this basic tenet of orthopedic surgery during his orthopedic residency. (Levine Dep., p. 21-22 at Ex. R) Dr. Spielman and Dr. Zardiackas also discussed this generally-accepted concept. (Spielman Aff., ¶ 4-5, 19 at Ex. H; Zardiackas Aff. ¶ 7, 20-22 at Ex. I)

Given Mr. Lieberman's failure to tie his opinion to the facts of the case and failure to rule out generally accepted, non-negligent reasons for the breakage of two of the ATB's screws implanted in plaintiff, his opinion is unreliable and should be excluded.

CONCLUSION

Based on the foregoing, an Order should be issued, pursuant to Rule 56 of the Federal Rules of Civil Procedure, granting summary judgment in favor of Synthes dismissing plaintiff's Complaint with prejudice; or, in the alternative, for an Order, pursuant to Federal Rules of Evidence Rules 702 and 703, precluding plaintiff's expert, Warren Lieberman, from testifying in this matter, or for a *Daubert* hearing to assess the admissibility of the opinions proffered by this expert, together with such other and further relief as this Court deems just and proper.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

----------x

Civil Action No.: 08 CV 2060 (JAP)

PROOF OF MAILING AND CERTIFICATE OF SERVICE

DOCUMENT ELECTRONICALLY FILED

I, BARRY GERSTMAN, hereby certify and affirm that a true and correct copy of the attached **BRIEF IN SUPPORT OF DEFENDANTS SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC'S MOTION FOR SUMMARY JUDGMENT AND TO PRECLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WARREN LIEBERMAN** was served via regular mail and electronically on this 26th day of February, 2010, upon the following:

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s/Barry Gerstman
BARRY L. GERSTMAN (BLG-3691)